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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,454	09/15/2003	James D. Murray	UCAL-286	4027

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,454	MURRAY ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,6,13-15,17-21,33,35,36 and 38-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,13-15,17-21,33,35,36 and 38-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2006 has been entered.

Claims 2, 4, 7-12, 16, 22-32, 34, 37 are cancelled. Claims 44-48 are new.

Claims 1, 3, 5, 6, 13-15, 17-21, 33, 35, 36, 38-48 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 6, 13-15, 17-21, 33, 35, 36, 38-48 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The final Written Description Examination guidelines that were published on January 5, 2001 (66 FR 1099; available at http://www.uspto.gov/web/menu/current.html#register).

The written description requirement for a claimed genus is satisfied by sufficient description of a representative number of species by actual reduction to practice and by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicant were in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

While the specification indicates that a transgene construct comprising a nucleic acid sequence encoding rat stearoyl CoA desaturase (SCD) was expressed in the mammary gland of mice and goats and the expression of rat SCD in milk of these transgenic animals resulted in a reduction of saturated fatty acids (SFA) and an increase in monounsaturated fatty acids (MUFA) and polysaturated fatty acids (PUFA), the art teaches that in many animals (including rat), there are multiple forms of SCD and

that the specificity of these SCDs for substrates is different, such that an artisan cannot reasonably predict which rat SCD to use to arrive at the claimed invention. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case, while the specification provides guidance for using a rat SCD to arrive at the claimed invention, the specification, in light of the art teaching that the family of SCDs, is wide and the biological targets which these SCDs catalyze an enzymatic reaction are different. The skilled artisan cannot envision all the possible SCDs and their biological targets, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be

unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, no stearoyl CoA desaturases meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1, 3, 5, 6, 13-15, 17-21, 33, 35, 36, 38-48 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record discussed in the Office Actions of September 2, 2004 and April 6, 2005 and for new reasons, below.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in

determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

While the specification teaches an artisan that transgenic mice and goats expressing a rat stearoyl-CoA desaturase (SCD) in the mammary gland results in milk that have lower overall levels of saturated fatty acids (SFA) and higher levels of monounsaturated fatty acids (MUFA) and polyunsaturated fatty acids (PUFA), the specification does not provide sufficient guidance for an artisan to predictably arrive at the claimed invention. The lack of guidance stems from the fact that some animals, such as rat, express multiple forms of SCD that it is unclear which form of SCD was used to obtain the claimed invention. According to the art at the time of filing, the rat expressed two forms of SCD (Mihara, 1990, J. Biochem, 108: 1022-1029). Mihara teaches that rat SCDI and SCDII are expressed in different tissues (Mihara, page 1028, 2nd col., 1st parag.) and while SCDI encodes SCD (Mihara, page 1028, 1st col., 1st parag. under Discussion), the function of SCDII was unclear (Mihara, page 1028, 2nd col., 3rd parag.). Mihara teaches that the functions of rat SCDII could range from Δ5 and Δ6-desaturations of fatty acids, Δ7 sterol 5-desaturation, and 4-methyl sterol oxidation in cholesterol biosynthesis, plasmalogen biosynthesis, phospholipids desaturations, as well as the terminal oxidation of the microsomal fatty acid elongation reaction (Mihara,

page 1028, 2nd col., 3rd parag.). As such, Mihara indicates that the biological function of SCDs is unpredictable. Ten years after Mihara indicated that the role of rat SCDII was unclear, the art continues to indicate that the role of other species of SCD expressed in animals is unclear because within the enzyme family, Δ6, Δ9, Δ12, Δ15, and other desaturases have different selectivities for the length of acyl chain, the position of double bond insertion, and the type of polar head group on the preferred substrate (Kim et al., 2000, Journal of Lipid Research, 1310-1316; page 1314, 2nd col., 1st parag. under "Catalytic selectivity of SCD isoforms"). In a working example, Watts and Browse, 2000, Biochemical and Biophysical Research Communications, 272: 263-269, teach that 3 SCD-like genes from C. elegans were isolated and characterized. While two SCD-like genes, fat-6 and fat-7, encode enzymes that show typical SCD activity, desaturating both 18:0 and 16:0, but with a preference for 18:0, fat-5 is specialized for medium chain saturated fatty acids (14:0-16:0) (Watts and Browse, page 267, 1st parag. under Discussion). Watts and Browse teach that as more and more SCDs are identified in rapidly progressing sequencing projects, the experimental results described in their publication demonstrate the importance of functional tests of enzyme activity and substrate specificity (Watts and Browse, page 267, 1st parag. under Discussion). As the teachings in the art apply to the instant invention, it is unclear whether rat SCDI or SCDII was used to arrive at the claimed invention (see specification, Example 1, pages 33-34). Nothing in the specification provides explicit guidance as to which rat SCD was used. Further, if rat SCDI was used, nothing in the specification provides guidance that overcomes the teaching in the art that rat SCDII or any other SCD could be used to

arrive at the claimed invention, such that the breadth of any SCD is enabled. It should be pointed out that because the specification is not enabling for the breadth of any SCD (see claim 6), that it follows that the specification is not enabling for the full breadth of any fatty acid desaturase (see claim 1).

Claims 1, 44 broadly encompass a non-human transgenic mammal comprising a transgene, wherein the transgene is not stably integrated in the genome (e.g. plasmid). While the specification provides guidance for a transgenic mouse and goat comprising in their genome, a transgene construct, the specification does not provide guidance as to how to reliably produce transgenic non-human mammals that express SCD in a mammary gland epithelial cell and results in milk comprising increased levels of MUFA and PUFA. The art at the time of filing teaches that introducing nucleic acid sequences to a host (i.e., gene therapy) is not routine in the art. Systemic administration of DNA constructs has proven to be difficult because of the rapid clearance of DNA from the circulation and the generally poor levels of expression following this method (Minchin et al., 2001, J. of Pharm. and Exp. Therap., 296: 1006-1012, see page 1006, 1st col., 1st parag.). As this applies to the instant invention, nothing in the specification provides guidance that systemic administration of a plasmid comprising a nucleic acid sequence encoding rat SCD operably linked to a mammary gland promoter is a viable way of delivering the plasmid to mammary gland epithelial cells and whether enough plasmid makes its way into the mammary gland epithelial cells such that SCD can be expressed at levels such that milk comprising a level of MUFA that is at least 5% higher than the level of MUFA in milk produce by an non-transgenic mammal of the same species is

achieved. For this reason, the specification does not provide guidance for a transgene construct that is not integrated in the genome.

Claims 13, 18, 45, 46 are drawn to methods of making a transgenic non-human mammal comprising a transgene, wherein the transgene is not stably integrated in the genome. Smith teaches that episomal vectors (e.g. plasmid vectors) behave in an unstable fashion. During development, plasmid copy numbers fluctuate and plasmids are lost from cells (Smith, 2004, Int. J. Med. Sci., 1: 76-91, page 83, under "5. Episomal Vectors"). The art also teaches that unintegrated copies of the microinjected transgene are degraded within four to five days (Page et al., 1995, Transgenic Research, 4: 12-17, page 16, 1st col., 2nd parag. under "Discussion). As these teachings apply to the instant invention, an artisan cannot predictably practice the claimed invention using episomal vectors.

Claims 18 and 46 are broadly drawn to cloning of any non-human mammal. However, the state of the art for production of any non-human mammal is not found to be predictable, utilizing any somatic cell donor, as instantly claimed. For example, Oback and Wells, 2002, Cloning and Stem Cells, 4: 147-168 review the state of the art for donor cells used in cloning and state, "currently, we do not know what makes a good donor cell. In mammals, more than 200 distinct cell types are plainly distinguishable by morphology and more will probably be discovered when better molecular markers become available. Less than 5% of these have been tested as nuclear donors, and they all support development to blastocysts; however, many repeatedly failed to generate viable offspring (Oback and Wells, page 147, 2nd col., 1st parag.)." Oback and

Wells further support the lack of teachings provided in the art with regard to donor cells that predictably result in live offspring by showing that in different animal species, different somatic donor cells have been tested with varying results. For example, Wakayama and Yanagimachi tested eight cell types in nuclear transfer (NT) methodology in mice, and found that live offspring were obtained from fibroblast, undefined fetal gonadal and cumulus cells. Further, Kato et al. tested somatic donor cells in cattle and found that all supported development to blastocysts but live offspring were obtained from cumulus, oviduct, skin and liver cells (Oback and Wells, pages 155-156). Further, Oback and Wells teach that deciding which cell to use as a donor cell in NT methods is not clear because the cells that have worked in certain species are not the same cells that work in other species, and that they are often dissimilar in their cell cycle stage and their cloning competence. Oback and Wells provide a summary of cloning efficiencies from various somatic donor cells (see Table 1). It is noted that different cell types provide different cloning efficiencies with regard to different animal species. Thus, when taken with the specification's lack of teachings or guidance to enable the full breadth of the claimed invention (of any somatic cell donor) and the state of the art's clear teaching of the unpredictability of using any somatic cell as a donor in NT methodology, and the unpredictability amongst species of animals in using different somatic cells, an artisan could not reasonably arrive at the claimed invention.

The unpredictability in the NT art is further supported by the post-filing art of Campbell et al., 2005, Reprod. Dom. Anim.,40: 256-268. Campbell et al. review the state of the art of NT, and particularly, with regard to the choice of a particular, suitable

donor cell, they teach that although different cultured cells, as well as some somatic cells can be used in NT, there are varying results using these cell types, and they state that, "unfortunately no conclusion can be made on what is the most appropriate cell type for SCNT (Campbell et al., page 261, see under, Selection and culture of a suitable donor cell)." Tian et al. 2003, Reprod. Bio. & Endocrin., 98: 1-7, also support the unpredictability in selection of an appropriate donor cell, they teach that somatic cells have varying cloning competence and that although specific cell types have found to be successful in producing cloned animals, "A clear consensus, however, has not been reached as to the superior somatic cell type for nuclear transfer." They compared various donor cell types from the same donor animal and conclude that the donor cell type can significantly affect embryo development, both *in vitro* and *in vivo* (Tian et al, pages 3-4, under, Cloning competence of various somatic cell types). Thus, specific guidance must be provided to enable the claimed invention in view of the unpredictable state of the art with regard to NT in general, and specifically, for the specific donor cell used. For example, Li et al., 2003, Reprod. Bio. & Endocrin., 84: 1-6, state that, "overall efficiency of nuclear transfer is still very low and several hurdles remain before the power of this technique is harnessed. Among these hurdles include an incomplete understanding of biologic processes that control epigenetic reprogramming of the donor genome following nuclear transfer. Incomplete epigenetic reprogramming is considered the major cause of the developmental failure of cloned embryos and is frequently associated with the disregulation of specific genes. At present, little is known about the developmental mechanism of reconstructed embryos. Therefore, screening strategies

to design nuclear transfer protocols that will mimic the epigenetic remodeling occurring in normal embryos and identifying molecular parameters that can assess the developmental potential of pre-implantation embryos are becoming increasing important (Li et al., abstract)." Li et al. further state that, "The factors involved in the success of NT are very complex. Although many protocols have been modified and utilized in the NT processes, some events continue to remain ill-defined (Li et al., page 1, 2nd col., parag. under Progress in Nuclear Transfer)." This further supports the unpredictability in the art - if it would be routine experimentation to produce cloned animals, then one could expect that any donor cell could be successfully used to produce any species of animal. Such has not been found to be the case. Li et al. teach, "the low efficiency and abnormal development of cloned animals are mainly due to incomplete reprogramming and abnormal gene expression." Li et al., page 2, 1st col., 2nd full parag. Li et al. further state, "most cloned embryos have been observed to fail to develop to term, and some of the surviving cloned animals have shown abnormalities. The major cause may reside in faulty or incomplete epigenetic reprogramming of the donor nucleus, which affects the gene expression needed for every developmental stage of cloned embryos and offspring. Most cloned embryos lose their developmental abilities during pre-implantation and gastrulation. Moreover, the surviving adults often show abnormalities (Li et al., page 2, col. 1-2, bridging parag.)." McEvoy et al., 2003, Reprod. Supp., 61:167-182 support this unpredictability, citing that the production of NT-derived ruminants is an inefficient process that generally fails to generate viable offspring. They suggest that after NT, fetal losses are due to significant developmental retardation and

placental inadequacies, and state the following, "Indeed, the fact that losses can occur at all stages and in various guises, ranging from gross degeneration of preimplantation embryos to sudden post-natal death of apparently normal offspring, confirms that NT procedures are frequently responsible for fundamental and far-reaching disruption of developmental norms. Intuitively, it could hardly be otherwise, given that the reconstructed egg comprises a severely traumatized host cytoplasm fused to a donor cell (or nucleus) with which, to a greater or lesser extent, depending on its origin, it is virtually incompatible from the outset. Therefore, the more remarkable phenomenon is that, against the odds, NT sometimes results in the generation of viable offspring (McEvoy et al., emphasis added, page 173, 2nd and 3rd parags. under Nuclear Transfer Technology)." Therefore, NT transfer is clearly not a method that only requires routine experimentation in order to practice, but a complex method that is unpredictable at various stages, as evidenced by the cited art.

The claims further encompass cloning of primates, which is found to be unpredictable for specific reasons. Vogel, 2003, Science, 300: 225-227 teach that Rhesus monkey nuclear transfer (NT)-generated embryos seemed normal at their early stages but were unable to develop further when implanted into a surrogate mother. This was because the cells had the wrong number of chromosomes, and that this aneuploidy resulted in the abortion of the fetus. This was found to also be the case with human NT embryos (Vogel, page 225, 1st col., 5th parag. to 2nd col., 1st parag.; also 2nd col., 4th parag.). Simerly et al., 2003, Science, 300: 297 teach that, "Primate NT appears to be challenged by stricter molecular requirements than in other animals ...

With current approaches, NT to produce embryonic stem cells in nonhuman primates may prove difficult - and reproductive cloning unachievable." See p. 297, 3rd col., last sentence. As the state of the art evidences, NT in primates is unpredictable, and the instant specification fails to provide teachings to show that primate NT using the claimed methods would result in pluripotent mammalian cells, it would have required undue experimentation for one of skill in the art to make and use the claimed invention.

Claims 18 and 46, step b, result in a tetraploid mammal, as the genetically modified nucleus from the genetically modified somatic cells is transferred into a single-celled embryo. The recipient cell would need to be enucleated before it can be used.

For these reasons, the specification does not provide guidance for an artisan to practice the claimed invention.

Response to Arguments

Applicant's arguments, filed February 6, 2006, with respect to claims 1, 3, 5, 13-15, 17-21, 33, 35, 36, 38-43 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 40 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18 and 40, steps a-c, use a

mammalian somatic cell (including human) comprising a genetic modification, wherein the nucleus of the mammalian somatic cell is used to make a non-human transgenic mammal. The resultant mammal of these steps would include human, which does not agree in scope with the preamble of the claim.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER